RESPONSE TO RESTRICTION REQUIREMENT

In the Office Action, the Examiner has requested that the Applicant make an election between the following three groups of claims, which the Examiner contends represent three independent or distinct inventions:

I. Claims 1-15 and 43-44, drawn to a method of delivering a pharmaceutical through a membrane, and a method of treating Gaucher's Disease, classified in class 514, subclass 2;

II. Claim 16-39, drawn to a therapeutic phospholipid composition, classified in class 514, subclass 2;

III. Claims 40-42, drawn to a polypeptide, classified in class 530, subclass 300.

Applicants respectfully traverse the restriction requirement for the following reasons. The Examiner contends that the three groups of claims represent three distinct inventions. The Examiner initially concedes that inventions I and II are related as product and process of use. However, the Examiner also maintains that these inventions can be shown to be distinct if the product, as claimed, can be used in a materially different process for using that product (MPEP §806.05(h)). The Examiner argues that the inventions of groups I and II are distinct since the product of invention II could be used to deliver a broad range of pharmaceutical agents for the treatment of other genetic diseases having non-overlapping patient populations, such as Sickle Cell Disease or Thalassemia, for example.

Invention I is drawn to a method of delivering a pharmaceutical through a membrane using a therapeutic phospholipid composition, and a method of treating Gaucher's Disease, which the Examiner indicates is in class 514, subclass 2. Invention II is drawn to a therapeutic phospholipid composition, also classified in class 514, subclass 2. The inventions of groups I and II (claims 1-15, 43-44 and 16-39, respectively) define a therapeutic phospholipid composition and methods of delivering a pharmaceutical agent through a membrane using the phospholipid composition of group II claims. The invention of group I defines a method of treatment using a therapeutic phospholipid composition, while group II relates to a therapeutic phospholipid composition. Therefore, if a complete search is done on invention II, which is directed to a therapeutic phospholipid composition, invention I will also be searched, since these claims relate to a method of use for a therapeutic phospholipid composition. In addition, as indicated by the Examiner, inventions I and II would require a search of the same class and subclass (class 514, subclass 2).

MPEP §803 indicates that even if a patent application contains independent and distinct inventions, those inventions should be considered together by the Examiner if he can do so without any undue burden. Therefore, even assuming arguendo that the claims of groups I and II do define two separate inventions, the Examiner can consider all of them without placing himself under an undue burden since they all relate to methods of treatment using the same therapeutic phospholipid composition and, as the Examiner has indicated, are searched in the same subclass.

The Examiner also concedes that the polypeptide of invention III is related to the process of invention I in that the polypeptide of invention III is a component of the process of invention I. However, the Examiner argues that the product of invention III may be used in materially different processes such as in a method of making an

antibody and as such, is patentably distinct from invention I. Claims 40-42 define polypeptide sequences specifically required by the method claims for invention I, i.e., a "fusogenic protein or polypeptide derived from prosaposin." Accordingly, if the invention of group I searched, the invention encompassed by group III will also be searched and the combining of these two groups of claims would clearly not represent an undue burden on the Examiner. Therefore, based on MPEP § 803, the claims of groups I and III of the present application should be considered together.

Alternatively, a search of the use of the polypeptides defined by group III would include a large part of the search required for group I claims which are directed to a method of using these polypeptides in combination with phospholipids for delivering a pharmaceutical agent. Consequently, the inventions defined by groups I and III could be considered together without placing any undue burden on the Examiner.

Finally, the Examiner concedes that the products of inventions II and III are related by the presence of the same polypeptide. But, the Examiner also maintains that the product of invention II is a composition designed for a specific function, whereas the product of invention III (the polypeptide) would have broader utility, and therefore would be useful in materially different processes and as such, the inventions are patentably distinct. Claims 40-42 define polypeptide sequences specifically required by the composition claims for invention II, i.e., a "fusogenic protein or polypeptide derived from prosaposin." Accordingly, if the invention of group II searched, the invention encompassed by group III will also be searched and the combining of these two groups of claims would clearly not represent an undue burden on the Examiner. Therefore, based on MPEP § 803, the claims of groups II and III of the present application could be considered together.

Since the several groups of claims defined by the Examiner can be considered together without placing any undue burden on the Examiner, the restriction requirement, which attempts to define three separate inventions, is not appropriate in the present case. Accordingly, withdrawal of this restriction requirement is requested and issuance of an office action covering claims 1-44 of the present application is earnestly requested.

In the event that the Examiner does not withdraw the restriction requirement and allow prosecution of claims 1-44, then at least Claims 1-15 and 43-44 and Claims 16-39 (groups I and II, respectively) describing a therapeutic phospholipid composition and a method of using the composition should be considered together in the present application, since, by the Examiner's own admission, these fall within the same class and subclass.

Finally, if the restriction requirement of the present Office Action is maintained, then Applicants provisionally elect claims of Group II, claims 16-39, for prosecution on the merits in the present application.

Applicant is aware of his obligations under 37 CFR 1.48(b) relating to inventorship issues. However, since this application has only a single inventor, this issue is moot.

Respectfully submitted,

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